I. REMARKS

Claims 1 and 8 to 13 are pending of which claims 1, 8, 10 and 13 are independent. No claims are amended, withdrawn, canceled, or added as a result of this response.

1. Claim Rejections under 35 U.S.C. § 101:

Claims 1 and 8 to 13 were rejected under 35 U.S.C. § 101, because the claimed invention is allegedly not supported by either a "specific, substantial, and credible utility or, in the alternative, a well-established utility." Office Action at page 2. The Applicants respectfully traverse these rejections.

The Examiner admits that the specification discloses many uses for polynucleotides (which include the claimed polynucleotide SEQ ID NO: 1) including identifying promoters involved in gene regulation, determining whether a plant contains a mutation, and acting as molecular tags to isolate genetic regions, isolate genes, map genes, and determine gene function. *Id.* However, the Examiner considers the disclosed utilities non-specific, applicable to polynucleotides in general, and not specific to the polynucleotide claimed. *Id.* at pages 2-3.

The Applicants have asserted throughout the specification that the claimed nucleic acid molecules provide identifiable benefits, for example use to identify the presence or absence of a polymorphism associated with, for example, cold-response genes, and use as a marker of cold tolerance. *See, e.g.*, specification at page 34, line 21 to page 35, line 8. Either of these utilities described alone is enough to satisfy Section 101 because these utilities are neither vague nor impractical. The Applicants need only establish a single utility to satisfy 35 U.S.C. § 101, and have done so in the present case.

Moreover, these utilities are not applicable to all polynucleotides in general because the claimed polynucleotides are obtained from cold-treated young maize seedlings. *See, for example*, specification at page 88 (Example 1). Therefore, they have utilities that are specific to them, utilities that are not shared by polynucleotides in general. For example, polymorphisms identified by the claimed nucleotides would not be identified by just any random, general polynucleotide.

The Examiner appears to challenge the credibility of the presently asserted utilities. Utility is determined "by reference to, and a factual analysis of, the disclosure of the application." *In re Ziegler*, 992 F.2d 1197, 1201, 26 U.S.P.Q.2d 1600, 1603 (Fed. Cir. 1993), *quoting Cross v. Iizuka*, 753 F.2d 1040, 1044, 224 U.S.P.Q. 739, 742 (Fed. Cir. 1985). The Examiner "has the initial burden of challenging a presumptively correct assertion of utility in the disclosure." *In re Brana*, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995). The utilities asserted in the specification must be accepted as factually sound unless the Patent Office cites information that undermines the credibility of the assertion. *Id.* The Examiner "must do more than merely question operability – [she] must set forth factual reasons which would lead one skilled in the art to question the objective truth of the statement of operability." *In re Gaubert*, 524 F.2d 1222, 1224-25, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975) (emphasis in the original); M.P.E.P. § 2107 ("Office personnel are reminded that they must treat as true a statement of fact made by an applicant in relation to an asserted utility, unless countervailing evidence can be provided ..."). Here, the Examiner has not even attempted to meet this burden. Unless and until the Examiner comes forth with evidence to rebut the objective truth of the utilities disclosed in the specification, this enablement rejection must be withdrawn as improper.

See In re Wright, 999 F.2d 1557, 1561-62, 27 U.S.P.Q.2d 1510, 1513 (Fed. Cir. 1993); *Ex parte Lemak*, 210 U.S.P.Q. 306, 307 (Bd. App. 1981) ("pure conjecture" does not substantiate rejection for lack of enablement).

The Applicants respectfully submit that the premise of the rejection under 35 U.S.C. § 101 is incorrect and the Applicants respectfully request withdrawal of this rejection.

2. Claim Rejections under 35 U.S.C. § 112, first paragraph (Enablement):

Claims 1 and 8 to 13 were rejected under 35 U.S.C. § 112, first paragraph, as not enabled by the specification.[1] The Examiner alleges that "since the claimed invention is not supported by either a "specific or substantial" asserted utility or a well established utility ..., one skilled in the art clearly would not know how to use the claimed invention." Office Action at page 3. The Applicants submit that this rejection is erroneous and has been overcome by the arguments stated above regarding utility because it is well-established law that "the enablement requirement is met if the description enables any mode of making and using the invention." *Johns Hopkins University v. CellPro*, 152 F.3d 1342, 1361, 47 U.S.P.Q.2d 1705, 1719 (Fed. Cir. 1998) (emphasis added), *quoting Engel Indus. v. Lockformer Co.*, 946 F.2d 1528, 1533, 20 U.S.P.Q.2d 1300, 1304 (Fed. Cir. 1991).

Using the *Wands* factors the Examiner takes the position "that it would require undue experimentation for one of skill in the art to perform the method of the claim as broadly written." Office Action at pages 4 to 6. Applicants respectfully disagree.

[1] The Examiner repeatedly refers to "fragments" of SEQ ID NO: 1. *See, e.g.*, Office Action pages 4-5. The Applicants respectfully remind the Examiner that the pending claims do not recite fragments of SEQ ID NO: 1.

Not only is it well established patent jurisprudence that the Applicants need not teach "conventional and well-known genetic engineering techniques" (*see, e.g., Ajinomoto Co. v. Archer-Daniels-Midland Co.*, 228 F.3d 1338, 1345, 56 U.S.P.Q.2d 1332, 1337 (Fed. Cir. 2000)), which would include the use of the claimed sequence with other nucleic acid sequences, but the Applicants also submit that an analysis of the criteria presented by *In re Wands* supports the Applicants' position that no undue experimentation would be required to make and use the claimed invention. *See In re Wands*, 858 F.2d 731, 737, 8 U.S.P.Q.2d 1400, 1404 (Fed. Cir. 1998).

The first *Wands* criterion is the quantity of experimentation necessary. The "make-and-test" quantum of experimentation is reduced by the extensive knowledge, *e.g.*, of conservative nucleotide substitutions, identification of an active site, and radiometric synthase assay conditions, to which a person of ordinary skill in the art has access. Performing routine and well-known steps cannot create undue experimentation even if it is laborious. *See In re Angstadt*, 537 F.2d 498, 504, 190 U.S.P.Q. 214, 218-219 (C.C.P.A. 1976). The second and third *Wands* criteria relate to the amount of direction or guidance given, and the presence or absence of working examples. The specification provides seven Examples, based on which one of ordinary skill in the art would be enabled to make and use the invention commensurate in scope with the claims.

The fourth, fifth and sixth *Wands* criteria focus on the nature of the invention, the state of the art and the relative skill in the art. The present invention relates to nucleic acid sequences, and the specification further describes amino acid sequences derived therefrom, antibodies, constructs and methods related thereto. *See, e.g.,* specification at page 29, line 5 through page

30, line 20 (describing polypeptide molecules and homologues), and page 34, line 3 through page 88, line 3 (describing use of the claimed nucleic acid molecules in methods of transforming plants). Practitioners in this art are guided by considerable knowledge and resources on the conditions and approaches that can be utilized to identify, confirm and introduce into other hosts, nucleic acid and amino acid sequences.

The seventh *Wands* criterion considers the predictability of the art. The Examiner has presented no evidence why one of ordinary skill in the art would not, for example, be able to predict substitutions or use the nucleic acid molecules of the present invention in the disclosed uses. The Applicants assert that the specification discloses sufficient guidance, for example through the seven Examples, to render these results predictable.

The subject matter of the pending claims has been disclosed in the specification in a manner adequate to enable one of skill in the art to make and use the claimed invention without undue experimentation. The Applicants have disclosed the complete chemical structure of SEQ ID NO: 1. For example, given the complete chemical structure of SEQ ID NO: 1, one of ordinary skill in the art would understand how to use the sequence of SEQ ID NO: 1 for the uses disclosed in the specification, *e.g.*, identifying promoters and associated regulatory sequences (page 36, line 16 through page 38, line 6), and identifying polymorphisms (page 39, line 6, through page 46, line 3). As stated above, the Applicants need not teach conventional and well-known genetic engineering techniques. Patents "are written to enable those skilled in the art to practice the invention, not the public." *W.L. Gore & Assoc., Inc. v Garlock, Inc.,* 721 F.2d 1540, 1556, 220 U.S.P.Q. 303, 315 (Fed. Cir. 1983). Furthermore, the performance of routine and well-known steps cannot create undue experimentation even if it is laborious. *See In re Wands*,

858 F.2d at 737, 8 U.S.P.Q.2d at 1404; *In re Angstadt*, 537 F.2d 498, 504, 190 U.S.P.Q. 214, 218-219 (C.C.P.A. 1976).

The Examiner states that "[t]he art recognizes that function cannot be predicted from structure alone." Office Action at page 6. The Examiner lists several scientific publications that apparently describe the difficulty in predicting protein function from structure/sequence in non-cold response genes but does not point to any difficulties in predicting function based on cold response gene sequences. This is not enough. An Examiner must accept a utility by an Applicant unless the Office has evidence or sound scientific reasoning to rebut the assertion. *See*, *In re Oetiker*, 977 F.2d 1443, 1445, 24 U.S.P.Q.2d 1443, 1444 (Fed. Cir. 1992), emphasis added. "More specifically, when a patent application claiming a nucleic acid asserts a specific, substantial, and credible utility, and bases the assertion upon homology to existing nucleic acids or proteins having an accepted utility, the asserted utility must be accepted by the examiner unless the Office has sufficient evidence or sound scientific reasoning to rebut such an assertion." Federal Register 66(4):1096, Utility Guidelines (2001), emphasis added. The Examiner has neither provided sufficient evidence nor sound scientific reasoning. What the Examiner has provided, at most, are a few general scientific publications indicating that sequence and structural homology apparently cannot rigorously be correlated with functionality.

"[A] 'rigorous correlation' need not be shown in order to establish practical utility; 'reasonable correlation' is sufficient." *See, Fujikawa v. Wattanasin*, 93 F.3d 1559, 1565, 39 U.S.P.Q.2d 1895, 1900 (Fed. Cir. 1996), emphasis added. The Examiner is respectfully reminded that any challenge to an Applicant's assertion of utility must be supported by sound scientific reasoning or sufficient evidence. The Examiner has provided neither and therefore

retains the initial burden of challenging the presumptively correct assertion of utility. *Brana*, 51 F.3d at 1567, 34 U.S.P.Q.2d at 1441. The Examiner cannot shift this burden to the Applicants.

For at least these reasons, the Applicants request reconsideration and withdrawal of the enablement rejections under 35 U.S.C. § 112, first paragraph.

3. Claim Rejections under 35 U.S.C. § 112, first paragraph (Written Description):

Claim 1 was rejected under 35 U.S.C. § 112, first paragraph, for containing subject "not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention."[2] Office Action at page 7.

The Examiner states that "[c]laim 1 is directed to a maize protein." and "[t]he breadth of enablement is not commensurate in scope with the claims." *Id.* The Applicants respectfully note that claim 1 recites "[a] substantially purified nucleic acid molecule that encodes a maize protein comprising a nucleic acid sequence of SEQ ID NO: 1 or its complement." It appears that the Examiner's position is that there is no written description of the nucleic acid sequence of SEQ ID NO: 1 which encodes the maize protein. This is clearly untrue because the specification demonstrates to one skilled in the art that the Applicants were in possession of the claimed genera of nucleic acid molecules.

The purpose of the written description requirement is to ensure that the inventor had possession of the claimed subject matter, *i.e.*, to ensure that the inventors actually invented what

[2] Although the quote appears to be directed to an Enablement rejection, the Examiner indicates that "[c]laim 1 is rejected under 35 U.S.C. 112, first paragraph (Written Description)." As such, the Applicants direct their arguments to the adequacy of the written description.

is claimed. *Gentry Gallery Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479, 45 U.S.P.Q.2d 1498, 1503 (Fed. Cir. 1998); *Lockwood v. American Airlines*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997); *In re Alton*, 76 F.3d 1168, 1172, 37 U.S.P.Q.2d 1578, 1581 (Fed. Cir. 1996). If a person of ordinary skill in the art would, after reading the specification, understand that the inventors had possession of the claimed invention, even if not every nuance, then the written description requirement has been met. *Alton*, 76 F.3d at 1175, 37 U.S.P.Q.2d at 1584. A person of ordinary skill in the art, after reading the specification as filed, would understand that the Applicants had possession of nucleic acid molecules encoding a maize protein comprising a nucleic acid sequence of SEQ ID NO: 1 and complements thereof. The Applicants have provided the nucleotide sequence of SEQ ID NO: 1 and complements thereof. Accordingly, the Applicants have demonstrated possession of the claimed invention.

The fact that the claims at issue are intended to cover molecules that include the recited sequence joined with additional sequences, or complements of the recited sequence, does not mean that the Applicants were any less in possession of the claimed nucleic acid molecules.[3] It is well-established law that use of the transitional term "comprising" properly leaves the claims "open for the inclusion of unspecified ingredients even in major amounts." *Ex parte Davis*, 80 U.S.P.Q. 448, 450 (B.P.A.I. 1948). *Accord PPG Indus. v. Guardian Indus.*, 156 F.3d 1351, 1354, 48 U.S.P.Q.2d 1351, 1353-54 (Fed. Cir. 1998); *Moleculon Research Corp. v. CBS*, 793 F.2d 1261, 1271, 229 U.S.P.Q. 805, 812 (Fed. Cir. 1986).

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[3] If the Examiner is arguing that no possession is shown because the precise claim language is not used in the specification, then it goes beyond what is required by the law. It is well-settled that the description of a claimed invention need not be *in ipsis verbis*. *Gentry Gallery v. Berkline Corp.*, 134 F.3d 1473, 1479, 45 U.S.P.Q.2d 1498, 1503 (Fed. Cir. 1998); *In re Alton*, 76 F.3d 1168, 1175, 37 U.S.P.Q.2d 1578, 1583 (Fed. Cir. 1996); *Martin v. Johnson*, 454 F.2d 746, 751, 172 U.S.P.Q. 391, 395 (C.C.P.A. 1972).

The Examiner states that the specification apparently "discloses very narrow working examples as compared to the wide breath (*sic*) of the claims". Office Action at page 7. The Applicants respectfully remind the Examiner that not only does the present application describe the nucleic acid molecule recited by claim 1 (SEQ ID NO: 1) but it also describes gene sequences, corresponding sequences from other species, mutated sequences, SNPs, polymorphic sequences, promoter sequences, exogenous sequences, and so forth (*see, e.g.,* specification at page 10, lines 1 to 7; page 22, line 9 through page 25, line 20; page 26, line 8 through page 27, line 20, and page 36, line 16 through page 38, line 6). The specification also describes appropriate hybridization conditions (*see, e.g.,* specification at page 19, line 1 through page 20, line 12); fusion protein or peptide molecules or fragments thereof encoded by the nucleic acid molecules of the present invention (*see, e.g.,* specification at page 29, line 23 through page 30, line 2); plant homologue proteins (*see, e.g.,* specification at page 30, lines 3 to 19); site directed mutagenesis of the claimed nucleic acid molecules (*see, e.g.,* specification at page 59, line 12 through page 60, line 7); and vectors comprising the claimed nucleic acid molecules and methods of transforming plants (*see, e.g.,* specification at page 64, line 13 through page 72, line 6). Moreover, the specification describes the construction of maize cDNA libraries and sequences obtained from maize cDNA libraries (*see, e.g.*, specification at page 34, line 4 through page 35, line 8 and page 88, line 5 through page 97, line 23).

The Federal Circuit determined in *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d 1316, 1321, 63 U.S.P.Q.2d 1609, 1610 (Fed. Cir. 2002) that the written description inquiry is a factual one determined on a case-by-case basis and that, in a given disclosure, "it may well be that various subsequences, mutations, and mixtures of those sequences are also described to one of

skill in the art." *Enzo*, 296 F.3d at 1326-1327, 63 U.S.P.Q.2d at 1615. Furthermore, it is well established that claims "may be broader than the specific embodiment disclosed in a specification. *Ralston-Purina Co. v. Far-mor-Co*, 772 F.2d 1570, 1575, 227 U.S.P.Q. 177, 179 (Fed. Cir. 1985) (*quoting In re Rasmussen*, 650 F.2d 1212, 1215, 211 U.S.P.Q. 323, 326 (C.C.P.A. 1981). The Federal Circuit has also elucidated a test for written description wherein a genus of nucleic acids may be described by a structural feature that distinguishes members of the claimed genus from non-members of the claimed genus. *Regents of the University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568-69, 43 U.S.P.Q.2d 1398, 1406 (Fed. Cir. 1997). The Applicants have satisfied that test for written description.

In particular, the Applicants have disclosed common structural features, for example the nucleotide sequence of SEQ ID NO: 1. Thus, for example, if a particular nucleic acid molecule contains the nucleotide sequence of SEQ ID NO: 1, then it is a member of the claimed genus of nucleic acid molecules comprising a nucleic acid sequence of SEQ ID NO: 1. Moreover, related nucleic acid molecules falling within the scope of the claimed invention are readily identifiable - they either contain the nucleic acid sequence of SEQ ID NO: 1 or they do not. The fact that the nucleic acid molecules may comprise additional sequences is beside the point. Such modifications are readily envisioned by one of ordinary skill in the art and disclosed throughout the specification.

In conclusion, the Applicants respectfully submit that claim 1 is supported by an adequate written description pursuant to the requirements of 35 U.S.C. § 112, first paragraph, and request reconsideration and withdrawal of this rejection.

II. CONCLUSION

In view of the foregoing remarks, the Applicants respectfully submit that the present application is now in condition for allowance, and notice of such is respectfully requested. The Examiner is encouraged to contact the undersigned at 202-942-5746 if any additional information is necessary for allowance.

Respectfully submitted,

Date: August 31, 2006

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